Arkansas Laboratory Medicine Sentinel Network

Survey Five

Patterns of Quality Assurance Activities in CLIA Waived Testing

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The release of the Institute of Medicine Report, "To Err is Human[1], raised interest in the occurrence of medical errors. Most of this focus has been on physician error, in the form of drug misuse, surgical error, and such. Laboratory mistakes resulting in inaccurate data used to diagnose disease or monitor therapy has not been subject to the same level of scrutiny.

Errors are not unique to medicine, and may be inevitable. They can occur a result of a variety of failures. Rasmussen describes three types of human behavior that contribute to different types of error. Skill based behavior is that which requires little or no conscious attention to the execution of a task. Rule based behavior requires the application of familiar procedures to decision making. Knowledge-based behavior describes the problem solving response to situations with no ready-made procedure available to address a problem[2]. These types of tasks create different types of errors. Reason describes three of these. A "slip" is an error of omission or commission that occurs due to a lack of technical skill. Rule-based errors occur when an incorrect protocol is chosen for a task, or the proper protocol is executed incorrectly. "Mistakes" are knowledge-based errors that occur because of a misjudgment in the absence of an established protocol[3]. Bosk, in Forgive and Remember, describes a similar taxonomy, where technical errors occur due to a lack of skill, and judgmental errors due to a lack of knowledge and experience. The former roughly corresponds to Reason's "slips," and the latter to rule-based errors and mistakes. He describes a third type of error, normative error, which involves violations of the basic standards of professional error[4]. Similarly, Reason believes that organizational issues can turn a mistake into an incident. An incident occurs when institutional factors prevent a mistake from being corrected. These factors can be described as the root cause of an error, a latent systematic fault that magnifies mistakes.

A number of normative factors in the health care industry make the system vulnerable to error. Health systems are composed of loosely coupled actors from various disciplines, each discipline having its own culture and set of norms. Information is informally exchanged between disciplines, and process changes are slow and often unreliable. Because the system is loosely coupled, the relationship between an action and its effect is often difficult to ascertain, which renders the system vulnerable to something "slipping between the cracks." Unless the organization has strong procedures for absorbing active

errors, it is vulnerable to a loss of control that transforms the error into a loss of system control that can result in harm to a patient[5]. In order to identify and recover from mistakes, and error-handling system is needed that prevents the transformation of a mistake into an adverse event[6,7] Within the healthcare system, there are cultural factors that contribute to an unwillingness to identify and admit mistakes. The risks of legal and financial liability and the difficulty in detecting mistakes, as well as the typical use of disciplinary action against a worker who admits a mistake make it unlikely that mistakes will be reported[8]. Thus, errors are more likely to be detected before causing harm in those organizations that have adopted formal normative systems for dealing with mistakes than in those that rely on informal error handling.

Laboratory error does occur, and can have an adverse effect on patient care.[9] Concerns over testing errors have been voiced for at least two decades[10]. In a study of hospital "stat" laboratories, Plebani and Carraro[11] found error rates of 0.47%, with 6.4% of these errors resulting in inappropriate care, and 19% resulting in additional inappropriate testing. This study was conducted in a medical school laboratory, which was expected to be relatively sophisticated. Mistakes included failures to meet European quality specifications for data precision and accuracy, as well as exceeding defined turnaround times. Similarly, Jenny and Jackson-Tarantino, studying failures in the New York State proficiency testing program, found an error rate of 0.73%, with common cause analytical error at a rate of 7,000 errors/million assays, and a failure to follow standard operating procedures at a rate of 300 errors per million assays, noting that many of the errors arose because of data acceptance limits larger than the suggested range for the test system[12].

The occurrence of error varies with the type of testing facility. Stull et al, using the proficiency testing results submitted to the Health Care Finance Administration (HCFA) as a part of the requirements of the Clinical Laboratory Improvement Act of 1988 (CLIA '88), found that hospital and independent reference laboratories were from 2-7 times less likely to produce an unsuccessful result than other types of laboratories. An unsuccessful result was defined as the failure of a laboratory to accurately report results for four out of five samples in the batch that constitutes a testing event.[13] Hurst et al found that the error rates were three times as high in physician office laboratories

(POLs) as in traditional laboratories, and 1.5 times as high in POLs that did not use technical personnel in a supervisory role as in those that did.[14]

The CLIA '88 regulations brought all medical testing into a common framework. Prior to these regulations, only traditional laboratories were subject to regulatory requirements for quality assurance practices. Testing facilities are classified according to the complexity of the testing performed rather than the organizational structure of the facility. This classification scheme is designed to assure that quality regulations are applied at an appropriate level for the test performed[15]. The CLIA program, or an equivilent such as that run by the College of American Pathologists, accredits laboratories performing higher complexity tests. These programs require quality assurance practices that become more stringent with increasing test complexity. Laboratories performing simpler tests can obtain a Certificate of Waiver from the CLIA program, which exempt the laboratory from most quality assurance requirements. As the number of tests classified as "Waived" and the practice of point-of-care testing have risen, concerns over the quality practices in these laboratories has grown. Several studies document poorer performance in waived or point-of-care testing operations. [16,17] In a Washington Department of Health study of Moderate and High Complexity laboratories which face stringent regulatory standards for quality assurance, it was found that laboratories state that they determine their quality control practices for waived tests primarily based on the regulatory requirements. The study found that even laboratories that reported following regulatory requirements varied widely in their practices.[18] This raises concerns that the data generated by Waived laboratories, which are subject to few if any real requirements to maintain a quality system, may not be of as high a quality as that generated by traditional laboratories and, more importantly, that differing normative standards for assessing data quality does not allow the laboratory or end user to determine the accuracy of the result.[19] The Waived level laboratories, which are expected to derive their quality norms from weaker regulatory requirements, are expected to adopt weaker standards for assuring data quality. Thus, an error is more likely to be transformed into an adverse event because the probability of a bad test result being transferred to a practitioner as "good" increases.

Bosk[20] defines a normative medical error as errors that challenge the "tacit background assumptions about how reality in a scene is constructed." Most literature on medical laboratory data focuses on technical errors inherent in the testing process. Quality Assurance activities are designed to identify these technical errors and allow them to be corrected before data is transferred to the health care provider for use in diagnosis or treatment. Within the healthcare system, this data is assumed to be accurate when presented for use. The normative role of the laboratory is to present data that is as accurate as the laboratory is capable of assuring. Failure to conduct quality assurance activities in the laboratory violates the norms expected of a laboratory and undercuts the assumption of data accuracy.

Most of the interest in medical error has focused on technical and judgmental errors by physicians in treatment and medication decisions. Perhaps a more important issue lies in the way underlying normative or cultural values can moderate the effects of these issues. Bosk notes that most technical and judgmental errors occur because of limitations in the skills of health care professionals. Some error of this sort will occur because of the inability to attain perfection. These errors can be caught and remedied if appropriate standards are used to check decisions. Violations of such normative standards, therefore, may be more serious than the primary technical errors they are designed to catch.

Examples of a normative error would include all cases in which a laboratory result was released to a medical caregiver where no quality assurance check (such as the use of an external check sample of known value to ascertain the accuracy of the measurement, use of instrumental procedural controls, or comparison to the patient history) was performed. This is distinguished from a pure technical error, such as obtaining an incorrect result on a test, in that the normative error prevents the laboratory from identifying and correcting the technical error. The normative error may occur even in the absence of the technical error, as the normative error is the failure to take proper action to ascertain whether the released data is accurate or inaccurate. In the absence of the normative error, the laboratory can correct the technical error. The normative error prevents even the identification of a technical error.

From a theoretical standpoint, laboratories adopt a set of normative behavioral standards that are encoded as a grammar of action in their everyday operating procedures. The performance of activities designed to identify flawed data represents a tangible manifestation of such a standard. Quality assurance checks are the means by which a laboratory that has a strong organizational ethos for accuracy assures that the inevitable technical and judgmental slips are not transformed into adverse events (Figure 1).

Examining the case of tests classified at the "waived" or "PPMP" levels can test this model. Medical facilities have a choice in adopting such normative standards for these tests. Since a PPMP or Waiver certificate does not explicitly require performance of quality assurance measures as the regulations do of laboratories credentialed at the Moderate or High Complexity levels, facilities can choose to not perform these tests[1]. LaBeau found that laboratories primarily determine the structure of their quality system according to regulatory requirements[17]. Lee and colleagues found that regulatory requirements may cause a laboratory to downgrade an certification level, but do not have a significant effect on the decision to upgrade certification[21]. Thus, laboratories at the Waived/PPMP level are less likely to have adopted a quality assurance system than laboratories performing the same test at a higher certification level.

Operationally, this can be determined by correlating the use of quality assurance measures with the certification status of the laboratory. These measures include comparison of results to patient history, use of procedural or electronic controls to assure that the proper test procedure is performed, and the use of liquid controls standards and blind performance evaluation standards to check measurement accuracy. Because waived and PPMP level tests are performed in labs at all certification levels, the higher certification laboratories which must adopt stricter quality systems to meet regulatory requirements serve as a useful control group. Certification level serves as a useful surrogate for organizational culture because the higher-level laboratories are known to have made a decision to adopt an error-handling system due to the certification requirements they have met. It is expected that, if laboratories at the Waived and PPMP choose that certification level to avoid implementing quality assurance

[1] Technically, a PPMP test is subject to the quality assurance requirements for a Moderate complexity test. In practice, standards are not as stringent, as the PPMP laboratory is not subject to regular inspection to assure compliance.

measures, a positive correlation will be seen between increased use of these tools and certification levels.

This relationship can be modeled with two hypothesis, and tested with the corresponding null hypothesis:

H_1: A positive correlation exists between having a Moderate or High-level certification and use of *any* quality assurance measure.

H_{-1}: Rates of tests for which *no* quality assurance measures are performed is identical between the Waived/PPMP and Moderate/High level facilities.

$H_{2:}$ The frequency of use of quality assurance measures, controlled for test, is higher in Moderate/High Complexity facilities than in Waived/PPMP facilities.

$H_{-2:}$ No difference exists in the frequency of use of quality assurance measures between the two types of facilities, when controlled by test.

Methodology

A survey was sent to 571 facilities in the state of Arkansas and in counties outside Arkansas that bordered Arkansas. These facilities included hospitals, independent laboratories, home health agencies, physician office laboratories, county health departments, nursing homes, and pharmacies that possessed a CLIA certification or certificate of waiver. The survey consisted of two parts. The first asked the facility to identify which waived tests were performed and which specific test system it used.

The second section asked the facilities to list the CLIA waived tests that were performed and asked which types of quality assurance activities were performed and at what frequency. The quality assurance activities included the following:

- Procedural Controls – Controls that are built into the testing device to assure that the reagents are active, added correctly, and that the system performs according to the manufacturers specifications.

- Electronic Controls – Inert, reusable devices such as cartridges, cassettes, test strips, etc., used to check instrument performance specifications.
- External Liquid Controls - Reference solutions not built into the testing device, but which are added in liquid form to the device in the same manner as a patient specimen.
- Comparison to Patient History – Correlation of the result with the patient presentation, history, or diagnosis.
- Proficiency Testing – Specimens purchased from a proficiency testing provider and analyzed without the analysts knowledge of the true value to measure the accuracy of the analytical system.
- Other – a catch-all category where the respondent was asked to list the quality assurance measures other than the preceding five used to assure data quality.

Frequencies were reported using standard categories – each kit, each test, daily, weekly, monthly, quarterly, semi-annually, and annually. Additionally, each respondent was asked to report certification status and type of facility.

Results

Responses were received from 213 facilities, for a response rate of 37.3%. The composition of facilities by type and certification are found in Table 1. Performance of waived tests was evaluated using the responses indicating the test or test kits used for each class of CLIA-waived test. For example, in the class of “Pregnancy Test”, the respondent could choose “test kits” such as “Visual Color Comparison Test” and “Bayer Clinitek 50.” Only four classes and kits were used by more than 40% of respondents. The significant responses are found in Tables 2 and 3.

Laboratories were classified as “waived” if they held a PPMP or Waiver CLIA Certificate, and “not waived” if they held a higher certification. For each test they performed, the test was coded as “QA performed” if any quality assurance test was performed at any frequency, and as “QA not performed” if no QA activities at all were reported. This is a very liberal standard, allowing classification as a QA performing laboratory if the QA activity consisted of as little as annually comparing one patient chart to the test result. This data was then analyzed with SPSS for Windows version 10.0, using the non-

parametric correlation statistics Kendall's Tau-b, Gamma, and Cramer's V (Table 4). The results indicated a statistically significant correlation between laboratories performing activities designed to ensure data quality and certification levels that require performance of such activities. This allows rejection of the null hypothesis H_{-1}, confirming H_1.

Rates of performance of quality assurance activities were also compared to determine whether the rate of use of a quality assurance test varied with the certification level of the laboratory. Test classes were examined which had a minimum of twenty responses from both Waived/PPMP level laboratories and facilities with higher certifications. Six test classes – urinalysis, strep antigen, pregnancy, occult blood, hemoglobin, and glucose – met this criteria. Because of ambiguity in the response definition (if a lab performs an assessment once per kit does it perform the assessment more or less than one that runs the measure once per day?), correlations were performed as if the data was at the nominal level in each variable. The null hypothesis, that the certification level cannot be predicted using the frequency of assessment, was tested using Goodman and Kruskel's tau, a nominal level non-parametric directional correlation coefficient with certification level as the dependent variable. Frequency relationships for statistically significant results are inferred from the pseudo-ordinal data. Results are presented in Tables 5-9.

No significant differences are seen at the 95% confidence limit in the rates of use of electronic controls or in correlating results to the patient's history. No significant difference is seen in the use of procedural controls except for the fecal occult blood test, where the non-Waived laboratories are significantly more likely to perform the control with each test performed. Uses of proficiency test are also significantly more likely and frequent for all the six test classes except hemoglobin. The rate of use of external liquid controls is significantly more likely for glucose, hemoglobin, and urinalysis, and significant at the 94.9% confidence level for the strep antigen test. Where differences occur between the two certification levels, higher classified facilities are more likely to perform quality assurance measures, and perform them more frequently, confirming hypothesis H_2.

Discussion

This study supports the theory that regulatory standards for quality assurance are a good surrogate for the study of normative standards for error prevention, and provides confirmation of Labeau's finding that laboratories are likely to adopt these normative standards based on regulatory requirements. Waived laboratories, which face few requirements for quality control of their testing systems, are also less likely to perform activities to assure data quality. Depending on the weight given to laboratory results in diagnostic or treatment decisions, laboratory errors may be more likely to advance to the stage of an adverse medical event. This suggests that future decisions regarding the issuing of waivers for test systems should be made very conservatively, with waivers only being issued to testing systems with a negligible probability of error, and little possibility of harm to a patient in the event of an erroneous result, which is the current CLIA regulatory criterion for such decisions. Adopting a less stringent standard for waivers, as has been proposed to the Food and Drug Administration, may increase the probability of medical errors compromising patient safety.

Figure 1. Model for Laboratory Error Processes

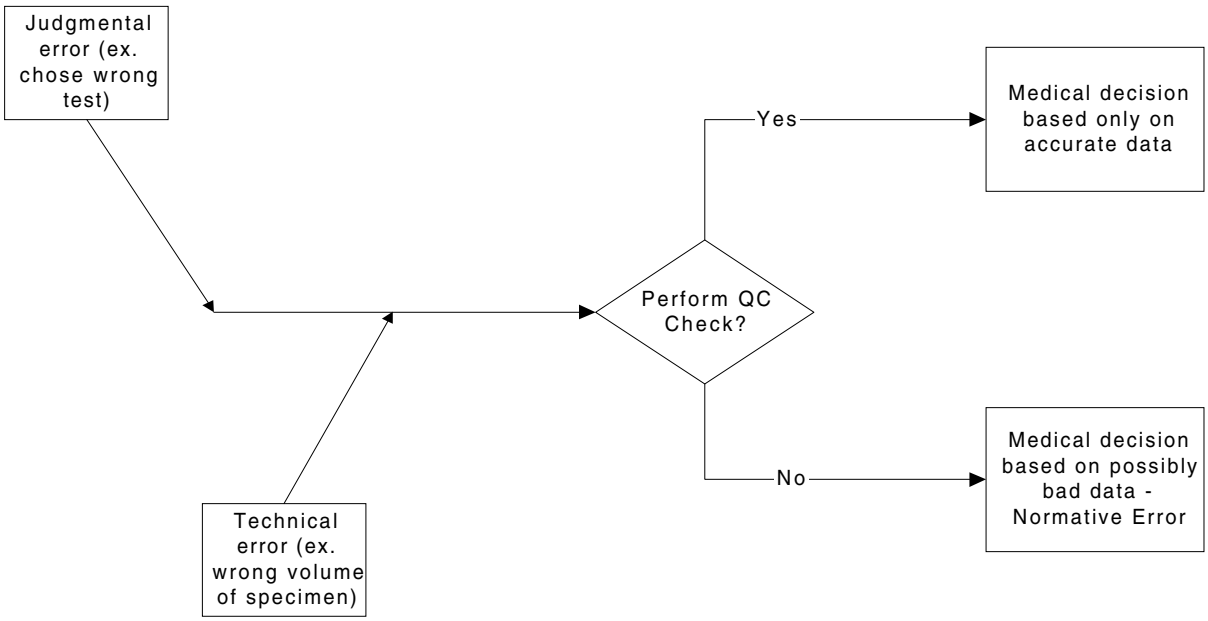

Table 1. Facility Type and Certification Status of Respondents.

Type of Facility	Number	Waiver	PPMP	Moderate	High	CAP	COLA	JCAHO	AABB	Other
Reference	4	2	0	0	1	1	0	1	0	0
Hospital	33	8	3	2	20	6	0	9	1	2
Physician Office Laboratory	79	20	5	37	9	0	6	9	0	3
County Health Department	42	16	0	24	2	0	0	0	0	0
Community Health Org.	6	0	0	6	0	0	0	6	0	0
Nursing Home	17	12	0	0	0	0	0	0	0	1
Home Health Agency	5	5	0	0	0	0	0	2	0	0
Other	18	14	0	1	1	0	0	2	0	3

Table 2. Test Classes Used by More than 20% of Respondents

Test Class	Frequency (%)
Glucose	70.7
Pregnancy	65.9
Occult Blood	61.2
Urinalysis	48.2
Strep Antigen	31.4
Erythrocyte Sedimentation Rate	28.0
Ovulation	28.0
Hemoglobin	22.8
Mononucleosis	22.3
Heliobacter pylori, whole blood	20.4

Table 3. Tests and Test Kits Used by more than 10% of Respondents

Test Class	Test or Kit	Frequency (%)
Occult Blood	Fecal Occult Blood	55.0
Glucose	FDA Approved Home Devices	51.7
Pregnancy	Visual Color Comparison Test	51.7
Urinalysis	Dipstick or Tablet Reagent	46.4
Ovulation	Visual Color Comparison Test	28.0
Erythrocyte Sedimentation Rate	Non-Automated	28.0
Hemoglobin	Hemocue Hemoglobin System	22.3
Strep Antigen	Quidel Quick View In-Line One Step	18.5
Heliobacter pylori, whole blood	Quidel Quick View One Step	16.6
Glucose	Hemocue B-Glucose Photometer	15.2
Pregnancy	Bayer Clinitek 50	14.2
Mononucleosis	Quidel CARDS OS	13.3
Hematocrit	Spun Microhematocrit	10.4

Table 4. Quality Assurance Usage and Laboratory Certification Status

	QA Performed	No QA Performed
Waived/PPMP	40	504
Higher Certification	40	232

Correlation Coefficients:

Coefficient	Value	Significance
Cramer's V	0.117	0.001
Kendall's τ-b	0.117	0.002
Γ	0.370	0.002

Table 5. Frequency of use of quality assurance measures –proficiency testing

Test	Waived (a)	Each test	Each Kit	Daily	Weekly	Monthly	Quarterly	Semi-Annually	Annually	Never	N=	Tau (b)	Significance
Glucose	No	0.0	0.0	1.3	0.0	0.0	31.6	1.3	1.3	64.5	79	0.132	0.001
	Yes	0.0	0.0	4.8	0.0	0.0	4.8	4.8	0.0	85.4	62		
Hemoglobin	No	0.0	0.0	0.0	3.2	0.0	19.4	3.2	0.0	74.1	31	0.150	0.118
	Yes	0.0	0.0	4.8	0.0	0.0	0.0	0.0	0.0	95.2	21		
Occult Blood	No	0.0	0.0	0.0	0.0	0.0	47.6	0.0	0.0	52.3	63	0.198	0.000
	Yes	0.0	0.0	0.0	0.0	0.0	6.3	6.3	0.0	87.5	32		
Pregnancy	No	0.0	0.0	0.0	0.0	0.0	51.2	1.3	0.0	47.4	78	0.152	0.001
	Yes	0.0	2.6	0.0	0.0	0.0	13.1	5.3	0.0	78.9	38		
Strep Antigen	No	0.0	0.0	0.0	0.0	0.0	65.1	2.3	2.3	30.2	43	0.153	0.050
	Yes	0.0	5.0	0.0	0.0	0.0	30.0	10.0	0.0	55.0	20		
Urinalysis	No	0.0	1.5	0.0	0.0	0.0	55.4	1.5	0.0	41.5	65	0.187	0.000
	Yes	0.0	2.3	0.0	0.0	2.3	13.9	7.0	0.0	74.4	43		

(a) Yes = Laboratory operates under a Certificate of waiver or PPMP Certificate, No= Laboratory is credentialed at the Moderate or High complexity level or by a private organization.

(b) Goodman and Kruse Tau, with certification status (see (a)) as the dependent variable.

Table 6. Frequency of use of quality assurance measures –correlation to patient history

Test	Waived (a)	Each test	Each Kit	Daily	Weekly	Monthly	Quarterly	Semi-Annually	Annually	Never	N=	Tau (b)	Significance
Glucose	No	37.9	0.0	8.8	1.3	0.0	2.5	3.8	0.0	44.3	79	0.036	0.411
	Yes	40.3	0.0	12.9	4.8	0.0	0.0	0.0	0.0	41.9	62		
Hemoglobin	No	35.4	0.0	12.9	0.0	0.0	0.0	0.0	0.0	45.2	31	0.015	0.869
	Yes	42.8	0.0	14.3	0.0	0.0	0.0	0.0	0.0	42.8	21		
Occult Blood	No	41.2	0.0	1.6	1.6	0.0	0.0	1.6	0.0	54.0	63	0.042	0.552
	Yes	50.0	0.0	3.1	0.0	3.1	0.0	3.1	0.0	43.8	32		
Pregnancy	No	47.4	0.0	3.8	0.0	0.0	1.3	0.0	1.3	46.2	78	0.034	0.564
	Yes	47.4	0.0	7.9	2.6	0.0	0.0	0.0	0.0	42.0	38		
Strep Antigen	No	48.8	0.0	7.0	0.0	0.0	0.0	0.0	0.0	44.2	43	0.010	0.896
	Yes	45.0	0.0	5.0	0.0	0.0	0.0	0.0	0.0	50.0	20		
Urinalysis	No	41.5	0.0	7.7	3.1	0.0	1.5	1.5	0.0	43.1	65	0.024	0.859
	Yes	37.0	0.0	9.3	0.0	0.0	0.0	0.0	0.0	51.1	43		

(c) Yes = Laboratory operates under a Certificate of waiver or PPMP Certificate, No= Laboratory is credentialed at the Moderate or High complexity level or by a private organization.

Goodman and Kruse Tau, with certification status (see (a)) as the dependent variable

Table 7. Frequency of use of quality assurance measures –Electronic Controls

Test	Waived (a)	Each test	Each Kit	Daily	Weekly	Monthly	Quarterly	Semi-Annually	Annually	Never	N=	Tau (b)	Significance
Glucose	No	6.3	4.2	22.7	3.8	0.0	0.0	1.3	1.3	62.0	79	0.023	0.775
	Yes	9.6	1.6	16.1	4.8	0.0	1.6	1.6	0.0	64.5	62		
Hemoglobin	No	0.0	3.2	54.8	0.0	0.0	0.0	0.0	0.0	41.9	31	0.054	0.267
	Yes	0.0	0.0	76.2	0.0	0.0	0.0	0.0	0.0	23.8	21		
Occult Blood	No	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100	63	N/A	N/A
	Yes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100	32		
Pregnancy	No	1.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	98.8	78	0.004	0.485
	Yes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100	38		
Strep Antigen	No	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100	43	N/A	N/A
	Yes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100	20		
Urinalysis	No	0.0	0.0	1.5	0.0	0.0	0.0	0.0	0.0	98.5	65	0.035	0.437
	Yes	2.3	0.0	2.3	0.0	2.3	0.0	0.0	0.0	93.0	43		

(d) Yes = Laboratory operates under a Certificate of waiver or PPMP Certificate, No= Laboratory is credentialed at the Moderate or High complexity level or by a private organization.

Goodman and Kruse Tau, with certification status (see (a)) as the dependent variable

Table 8. Frequency of use of quality assurance measures –Procedural Controls

Test	Waived (a)	Each test	Each Kit	Daily	Weekly	Monthly	Quarterly	Semi-Annually	Annually	Never	N=	Tau (b)	Significance
Glucose	No	6.3	0.0	8.9	1.3	0.0	0.0	1.3	1.3	83.5	79	0.063	0.261
	Yes	12.9	1.6	11.3	3.2	1.6	1.6	1.6	0.0	66.1	62		
Hemoglobin	No	0.0	3.2	15.6	0.0	0.0	0.0	0.0	0.0	77.4	31	0.014	0.701
	Yes	0.0	0.0	19.0	0.0	0.0	0.0	0.0	0.0	80.9	21		
Occult Blood	No	87.3	1.5	3.2	0.0	0.0	0.0	0.0	0.0	7.9	63	0.183	0.001
	Yes	53.1	0.0	3.1	0.0	0.0	0.0	0.0	0.0	43.8	32		
Pregnancy	No	1.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.8	78	0.063	0.205
	Yes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	28.9	38		
Strep Antigen	No	83.7	9.3	0.0	2.3	0.0	0.0	0.0	0.0	4.6	43	0.101	0.182
	Yes	80.0	0.0	5.0	0.0	0.0	0.0	0.0	0.0	15.0	20		
Urinalysis	No	4.6	0.0	3.1	0.0	0.0	0.0	0.0	0.0	92.3	65	0.032	0.325
	Yes	11.6	2.3	2.3	0.0	2.3	0.0	0.0	0.0	93.0	43		

(e) Yes = Laboratory operates under a Certificate of waiver or PPMP Certificate, No= Laboratory is credentialed at the Moderate or High complexity level or by a private organization.

Goodman and Kruse Tau, with certification status (see (a)) as the dependent variable

Table 9. Frequency of use of quality assurance measures –External Liquid Controls

Test	Waived (a)	Each test	Each Kit	Daily	Weekly	Monthly	Quarterly	Semi-Annually	Annually	Never	N=	Tau (b)	Significance
Glucose	No	7.6	3.8	64.6	11.3	1.3	0.0	0.0	0.0	11.4	79	0.124	0.015
	Yes	12.9	1.6	11.3	3.2	1.6	1.6	1.6	0.0	27.4	62		
Hemoglobin	No	3.2	9.7	38.7	0.0	0.0	0.0	0.0	0.0	48.3	31	0.235	0.042
	Yes	0.0	0.0	9.5	0.0	0.0	4.8	0.0	4.8	81.0	21		
Occult Blood	No	3.2	11.1	3.2	0.0	0.0	0.0	0.0	0.0	85.7	63	0.076	0.066
	Yes	15.6	6.3	0.0	3.1	0.0	0.0	0.0	0.0	75.0	32		
Pregnancy	No	2.6	44.9	3.8	0.0	0.0	0.0	0.0	0.0	48.7	78	0.070	0.089
	Yes	2.6	21.0	7.8	0.0	2.6	0.0	0.0	0.0	65.8	38		
Strep Antigen	No	2.3	58.1	2.3	2.3	0.0	0.0	0.0	0.0	37.2	43	0.152	0.051
	Yes	15.0	25.0	5.0	0.0	5.0	0.0	0.0	0.0	50.0	20		
Urinalysis	No	1.5	12.3	44.6	4.6	1.5	0.0	0.0	0.0	35.3	65	0.144	0.009
	Yes	0.0	7.0	13.9	7.0	4.7	0.0	0.0	0.0	67.4	43		

(f) Yes = Laboratory operates under a Certificate of waiver or PPMP Certificate, No= Laboratory is credentialed at the Moderate or High complexity level or by a private organization.

Goodman and Kruse Tau, with certification status (see (a)) as the dependent variable

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